Lashify v. ITC (Fed. Cir. 2025)

Joe Sherinsky

Assistant General Counsel, Mitsubishi Chemical America

November 5, 2025

Domestic Industry Overview

- Must exist at time complaint filed or be in the process of being established
  - 19 U.S.C. § 1337(a)(2)
- **Two prongs to DI** – Economic and Technical
  - **Economic Prong**
    - "Significant" investment in plant and equipment
    - "Significant" employment of labor or capital
    - "Substantial" investment in R&D or licensing
      - Non-practicing entities may rely solely on in investment in licensing activities to satisfy DI. *See*, *e.g.*, *Digital Satellite System (DSS) Receivers*, 337-TA-392, ID.
  - **Technical Prong**
    - Practice at least one valid, enforceable claim per patent
- **Injury**
  - Presumed for infringement of patent, trademark, registered IP
  - Must be shown for other unfair claims—trade secret misappropriation, etc.

Pre-*Lashify* Domestic Industry

- **General Standard:** For domestic industry, activities and their related expenditures must be "distinguishable from those of a mere importer." See *Schaper Mfg. Co. v. ITC*, 717 F.2d 1368, 1372-73 (Fed. Cir. 1983).
- **Prior to *Lashify*:** No bright-line rule to determine whether claimed activities are different from those of a mere importer, but activities such as sales and marketing, warehousing, quality control, distribution were generally not considered distinguishable from the activities of a mere importer.
- **Differing Views:** "Sales and marketing investments, ***when combined with other qualifying domestic investments or activities***, can be credited in determining whether a domestic industry exists." Commissioner Schmidtlein in *Certain Botulinum Toxin Prods., Inv.* No 337-TA1145, Comm'n Op. at 47 n.35 (Jan. 31, 2021).

Lashify Background

- **The Complainant and Conflict:** Lashify sought to bar the importation of eyelash extensions (plus cases and applicators). Lashify manufactured its products abroad but had substantial US sales and marketing
- Following its traditional approach the ITC denied an exclusion order for lack of DI.
- **The Federal Circuit reversed** on March 5, 2025, rewriting long-standing ITC precedent. *Lashify v. ITC*, No. 23-1245 (Fed. Cir. Mar. 5, 2025).
- **"There is no carveout of employment of labor or capital for sales, marketing, warehousing, quality control, or distribution," and "no suggestion that such uses, to count, must be accompanied by significant employment or other functions, such as manufacturing.“**
- *ITC sought en banc rehearing in May—denied in June, settled in August 2025*

Opening ITC's Door to Small Companies

- ***Lashify*, together with *Wuhan Healthgen Biotechnology Corp. v. ITC* (Fed. Cir. 2025),** are reshaping the ITC landscape for smaller companies.
- ***Wuhan*** weighed in on **significance and substantiality*:***
  - "Small market segments can still be significant and substantial enough to satisfy the domestic industry requirement. A finding of domestic industry cannot hinge on a threshold dollar value or require a rigid formula; rather, the analysis requires a holistic review of all relevant considerations that is very context dependent."
- Some quantitative factors for ***significance and substantiality*** determination:
  - Investment-to-revenue ratio
  - Comparison of domestic investments to total (*i.e.*, domestic plus foreign) investments
  - Value added by domestic operations
- The Federal Circuit explained that lower dollar investments in domestic industry can be sufficient.
  - "Though the dollar amounts of [Complainant's] investments are small, the Commission found all of the investments are domestic, all market activities occur within the United States, and the high investment-to-revenue ratios indicate this is a valuable market. Under these circumstances, there is substantial evidence for the Commission's finding that the domestic industry requirement is satisfied."

Recentive Analytics v. Fox Corp. (Fed. Cir. 2025)

Antony Pfeffer

General Counsel, Tractable

November 5, 2025

Subject Matter Eligibility Refresh

- Patent eligibility under 35 U.S.C. § 101 requires that an invention fall within one of four statutory categories: process, machine, manufacture, or composition of matter.
- Patent eligibility analysis involves the two step ***Alice/Mayo* Framework**:
  - **Step 1:** Is the claim directed to an abstract idea, law of nature, or natural phenomenon?
  - **Step 2:** Does the claim involve something more that amounts to an "inventive concept"?
- "If the claims are directed to a patent-ineligible concept, we assess the 'elements of each claim both **individually** and **as an ordered combination**' to determine whether they possess an '**inventive concept'** that is 'sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself.'"

Recentive Background

- **The Complainant and Conflict:** Recentive sued Fox for infringement of four ML-related patents.
  - Family #1: Machine Learning Training Patents (U.S. Patent Nos. 11,386,367 and 11,537,960), directed towards systems and methods for determining event schedules by dynamically generating optimized event schedules for live events using machine learning models trained on historical data.
  - Family #2: Network Map Patents (U.S. Patent Nos. 10,911,811, and 10,958,957) directed towards automatically and dynamically generating "network maps" that determine which programs are displayed on which channels according to geographic markets and timings.
- D. Del. District Court found claims ineligible under § 101 (abstract ideas, no inventive concept); **case dismissed**, leave to amend denied.
- ***Recentive* is the first case in which the Federal Circuit formally applied the *Alice* Framework to an AI patent.**
- The Federal Circuit **affirmed dismissal** and denial of leave to amend.
- The Federal Circuit held, "claims that do no more than apply established methods of machine learning to a new data environment" are patent ineligible under 35 U.S.C. § 101.

Old Rules, New Tech – Applying *Alice* to ML

- **<u>Step 1</u>: Is the claim's character as a whole directed to excluded subject matter (*e.g.*, abstract idea)?**
- "In the context of software patents (***which includes machine learning patents***), the step-one inquiry determines 'whether the claims focus on 'the specific asserted improvement in computer capabilities . . . or, instead, on a process that qualifies as an abstract idea for which computers are invoked merely as a tool.'"
- The Federal Circuit found that Recentive's claims were directed to abstract Ideas – they are directed to using **generic ML technology** for generating schedules in a new environment.
- **What is conventional or generic in ML Technology?**
  - "Requiring '***any*** suitable machine learning technology . . . such as, for example: a gradient boosted random forest, a regression, a neural network, a decision tree, a support vector machine, a Bayesian network, [or] other type of technique.'"
  - "Processes and logic flows" … "performed by ***one or more programmable processors*** executing one or more computer programs to perform actions by operating on input data and generating output."
  - "Processors suitable for the execution of a computer program include . . . both ***general and special purpose*** microprocessors, and ***any*** one or more processors of *any* kind of digital computer."
  - "Iterative training using selected training material and dynamic adjustments based on real time changes"

Old Rules, New Tech – Applying *Alice* to ML

- **<u>Step 1</u>: Is the claim's character as a whole directed to excluded subject matter (*e.g.*, abstract idea)?**
- **Applying existing principles:**
  - Generic implementation of ML/computer ≠ transformation of an abstract idea into non-abstract. *See e.g., In re Bd. of Trs. of Leland Stanford Junior Univ.,* 991 F.3d 1245 (Fed. Cir. 2021); *Enfish, LLC v. Microsoft Corp.,* 822 F.3d 1327 (Fed. Cir. 2016).
  - Generic steps of using ML/computer ≠ transformation of an abstract idea into non-abstract. *See e.g., IBM v. Zillow Grp., Inc*. 50 F.4th 1371 (Fed. Cir. 2022)
  - Limiting abstract ML to a particular field of use ≠ transformation of abstract into non-abstract. *Intell. Ventures I LLC v. Capital One Bank (USA),* 792 F.3d 1363 (Fed. Cir. 2015).
  - Applying existing technology to a novel database ≠ eligibility. *See e.g., SAP Am., Inc. v. InvestPic, LLC* 898 F.3d 1161 (Fed. Cir. 2018). The Federal Circuit held, these "cases are equally applicable" to ML.
  - Efficiency gains/speeding up human activity ≠ patent eligible. *See e.g., Content Extraction*, 776 F.3d at 1347; *Dealertrack, Inc. v. Huber.,* 822 F.3d 1327 (Fed. Cir. 2016).
  - ML model being 'iteratively trained' or dynamically adjusted in the … patents ≠ a technological improvement…, [and] "are incident to the very nature of machine learning."

Old Rules, New Tech – Applying *Alice* to ML

- **<u>Step 2</u>**: Do "the elements of the claim both individually and as an ordered combination' to determine whether the additional elements 'transform the nature of the claim' into a patent-eligible application?" (internal citations omitted).
- **The Federal Circuit said No.**
  - "[N]othing in the claims, whether considered individually or in their ordered combination, that would transform the Machine Learning Training and Network Map patents into something '**significantly more'** than the abstract idea of generating event schedules and network maps through the application of machine learning."
- **Federal Circuit Precedent Applied to ML:**
  - Transforming the nature of a claim "into a patent-eligible application requires more than simply stating the abstract idea while adding the words **'apply it.**'" *Trinity,* 72[11] F.4th at 1365

AI/ML at the PTO: Practice Over Precision

- **USPTO Memorandum (Aug. 2025)**
- **No new rules, but specific instructions for evaluating ML/AI claims.**
  - Carve out from mental process analysis by allowing a finding that AI/ML technology that cannot be performed mentally or with pen and paper ≠ mental processes.
- **Recitation v. Involvement:**
  - ***Recite*** a judicial exception (*i.e.,* naming a specific mathematical operation) → requires further analysis of the claim ***as a whole*** to determine whether ***the whole claim*** is directed to the judicial exception.
  - Merely ***involve*** a judicial exception → patent eligible and no further patent eligibility analysis necessary.
- ***Ex Parte Desjardins,* Appeal 2024-000567 (Decided Sept. 26, 2025):** Non-precedential decision, finding **patent eligibility** where there is an **abstract idea** (*i.e.*, a mathematical concept) but a **practical application to** improve the ML model's operation.

Regents of the Univ. of California (CVC) v. Broad Inst. (Fed. Cir. 2025)

Angie Verrecchio

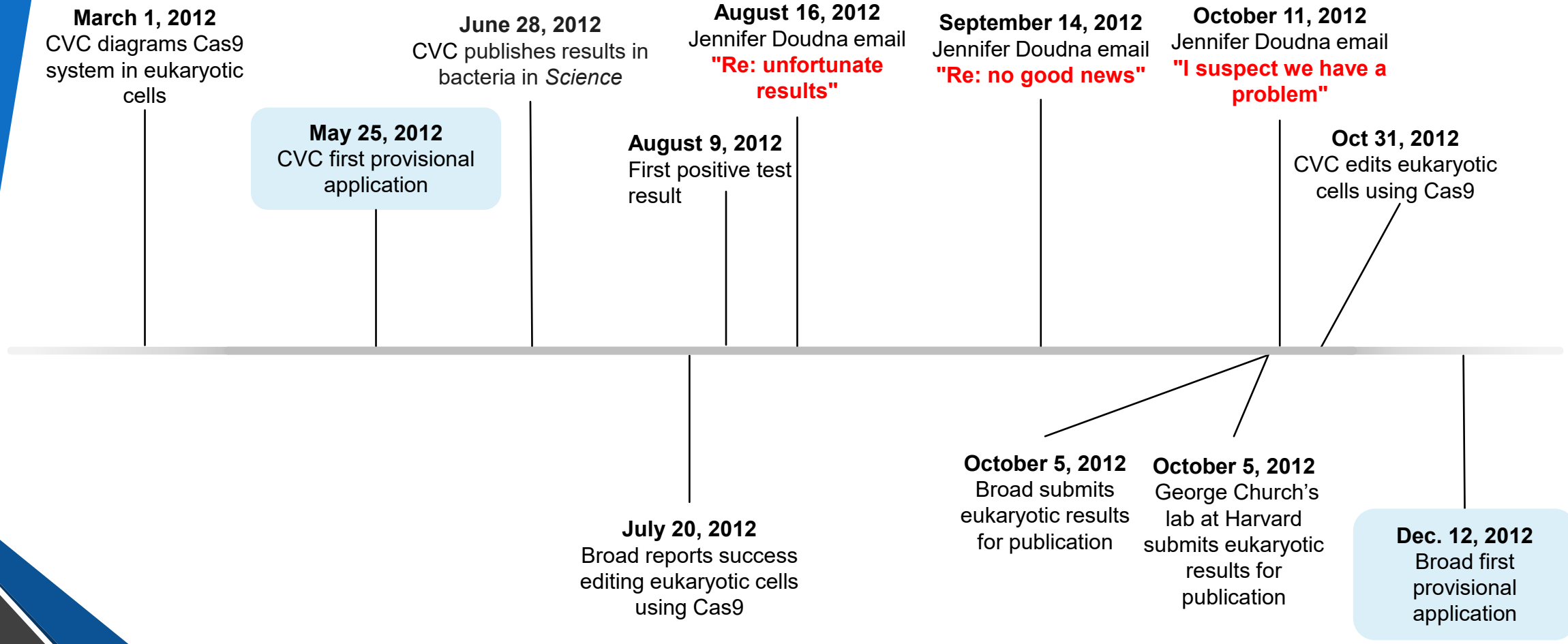
Assistant General Counsel, Johnson & Johnson

November 5, 2025

Background

- March 2012: Drs. Jennifer Doudna and Emmanuelle Charpentier describe Crispr-Cas9 system and diagram experiments using it in eukaryotic cells
- Summer–Fall 2012: scientists from six different laboratories, including CVC, use the system to edit DNA in eukaryotic cells
- 2019: USPTO declared interference proceeding between CVC and the Broad Institute re: Crispr-Cas9 in eukaryotes
- 2020: Drs. Doudna and Charpentier receive the Nobel Prize for Crispr-Cas9
- 2022: PTAB rejected the argument that Drs. Doudna and Charpentier of CVC were the first to conceive, determining Broad had priority over CVC
- 2022: CVC appealed; amicus briefs filed by Nobel laureates and Regeneron
- 2025: Federal Circuit decision; reversed PTAB and remanded

Timeline


March 1, 2012
CVC diagrams Cas9 system in eukaryotic cells
May 25, 2012
CVC first provisional application
June 28, 2012
CVC publishes results in bacteria in *Science*
August 9, 2012
First positive test result
August 16, 2012
Jennifer Doudna email
"Re: unfortunate results"
July 20, 2012
Broad reports success editing eukaryotic cells using Cas9
September 14, 2012
Jennifer Doudna email
"Re: no good news"
October 5, 2012
Broad submits eukaryotic results for publication
October 11, 2012
Jennifer Doudna email
"I suspect we have a problem"
October 5, 2012
George Church's lab at Harvard submits eukaryotic results for publication
Oct 31, 2012
CVC edits eukaryotic cells using Cas9
Dec. 12, 2012
Broad first provisional application

CVC Conception Document

New idea: adapt the CsnI/Cas9 system as a gene-targeting tool in mammalian cells, e.g. in embryonic or induced pluripotent stem cells, especially in those where homologous recombination is not efficient.

→ use CsnI/Cas9 to make a programmed double-stranded break to induce repair by homologous recombination

→ rely on homologous recombination to "repair" cleaved DNA based on an exogenous source (e.g. plasmid, viral vector)

Potential uses:

→ gene knock-outs / deletions
→ gene knock ins – introduce transgenes in a seq. specific position

→ gene repair – correct point mutations.

Signed: (MARTIN JINEK), 1st March 2012

Witnessed: RACHEL HAURWITZ 3/1/2012
Samuel H. Sternberg 3/1/12

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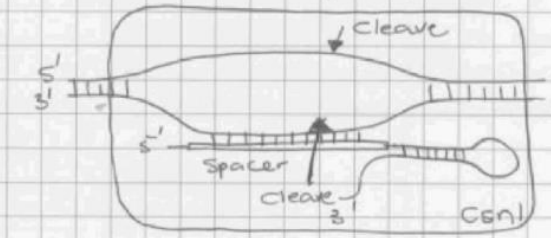
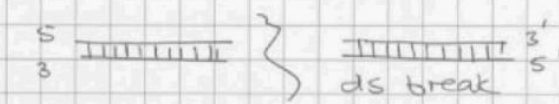
Next set of experiments

→ test that crRNA/tracrRNA hybrid constructs work in vitro

→ test whether the strategy can be used to induce DSBs in mammalian cells in a sequence-specific fashion.





repair by recombination

Jennifer Doudna Emails

NYIPLA
The New York Intellectual Property Law Association®

On Aug 16, 2012, at 4:00 PM, "Aaron Cheng" <acheng2@berkeley.edu> wrote:

> Hi Jennifer and Martin,
>
> I won't mince words - unfortunately, the experiment testing
> homology-directed repair using the RFP donor plasmid for CLTA shows that
> the current constructs could not mediate repair (see attached pdf).
>
> I had the forsight to save a portion of the cells for DNA analysis - so
> for completeness sake, I will assay them for Cas9-mediated cleavage. This
> will tell us whether or not it is a cleavage or repair problem.
>
> Your thoughts will be much appreciated.
>
> Feeling a bit sad,
> -Aaron
> <15Aug12_Doudna_CLTAHDR_

From: Jennifer Doudna <jadoudna@gmail.com>
Sent: Thursday, August 16, 2012 4:06 PM
To: Aaron Cheng <acheng2@berkeley.edu>
Cc: Jennifer Doudna <doudna@berkeley.edu>; Martin Jinek <jinek@berkeley.edu>; David Drubin <drubin@berkeley.edu>
Subject: Re: unfortunate results

Shucks! I guess it would have been too easy of it worked the first time...
I'll think on this and get back to you - my quick take is, maybe try again with improved Cas9 expression?

Sent from my iPhone

Jennifer Doudna Emails

NYIPLA
The New York Intellectual Property Law Association®

On Sep 15, 2012, at 4:03 AM, "Aaron Cheng" <acheng2@berkeley.edu> wrote:

> Hi all,
>
> Unfortunately, no cleavage for any RNA chimeras, despite using the codon-optimized Cas9 constructs this time. See attached.
>
> Quick thoughts:
>
> Martin - were you ever able to do some northerns to see if the RNAs are being expressed robustly and intact?
>
> Jennifer/Doudna - do we know for sure that the RNAs are localized to the nucleus? if not, is there a motif we can append to make sure that it does?
>
> :(

From: Jennifer Doudna <jadoudna@gmail.com>
Sent: Friday, September 14, 2012 4:30 PM
To: Aaron Cheng <acheng2@berkeley.edu>
Cc: Jennifer Doudna <doudna@berkeley.edu>; Martin Jinek David Drubin <drubin@berkeley.edu>
Subject: Re: no good news.

Hi Aaron - taking a step back, have you tried simply repeating the original experiment using increasing amounts of the plasmids encoding the chimeric RNA and the original Cas9 construct? We discussed this when we met in David's office a few weeks ago, and I think this is important to do, just to show reproducibility and rule out any possible ZFN contamination, etc. Once you have done this and assuming you see the same result as before, you can then do a side by side expt with the original and new versions of the Cas9 construct. Since there are so many variables in these experiments, I think we have to try to move forward in a stepwise fashion as much as possible.

As for RNA localization, I think we're hoping that the Cas9 protein binds the RNA such that the RNP is transported into the nucleus. I wonder if having a too-efficient NLS on Cas9 is actually counterproductive, if it means that Cas9 is transported before it has a chance to find and bind the guide RNA... Thoughts?

Best - Jennifer

Jennifer Doudna Emails

On Oct 11, 2012, at 5:15 AM, Jennifer Doudna <jadoudna@gmail.com> wrote:

> Hi Alex and Aaron - thanks for sending your results, although it's disappointing not to see Cas9-mediated cleavage in these experiments. Aaron, I'm wondering if you think there is anything different about the way you did the experiment back in August, when it appeared that there was some cleavage with the CLTA6 guide? Or could that result have been due to a contamination, say with the ZFN sample -? And it will be interesting to see the result from the RNA transfection experiment. Is it worth trying the transfections again with the codon-optimized Cas9? As we have discussed, I still think the problem may be with the assembly and localization of the Cas9 RNP - either due to degradation of the guide RNA, failure to assemble with Cas9 or failure of the RNP nuclear localization. I will think on this on my way back to SF tonight, and we can meet soon to discuss.
> Best - Jennifer
>

On 11 Oct 2012, at 15:08, Jennifer Doudna wrote:

> Hi Martin - great news about your progress with the xtals, fingers crossed for the next ALS trip...
>
> As for Cas9 in mammalian cells, I completely agree with your analysis and suspect that one or more aspects of the RNA expression/stability/Cas9 assembly/localization are problematic.
>
> It would be great to test some alternate designs of the guide RNA in vitro - perhaps this is something Alex could do, using target plasmids you already have available? Maybe we could also try this in cell extracts? We can discuss further tomorrow - 10 am OK?
>
> Best - Jennifer

CVC v. Broad (PTAB Decision 2022)

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Nineteen Hundred and Twenty-two

"***It is not sufficient for CVC to show only that its inventors conceived of the mechanics of a CRISPR-Cas9 system.*** To have conceived of an embodiment of Count 1 they must have had a definite and permanent idea of an operative invention, that is of a system ***they knew*** would produce the effects on genes in a eukaryotic cell recited in Count 1."

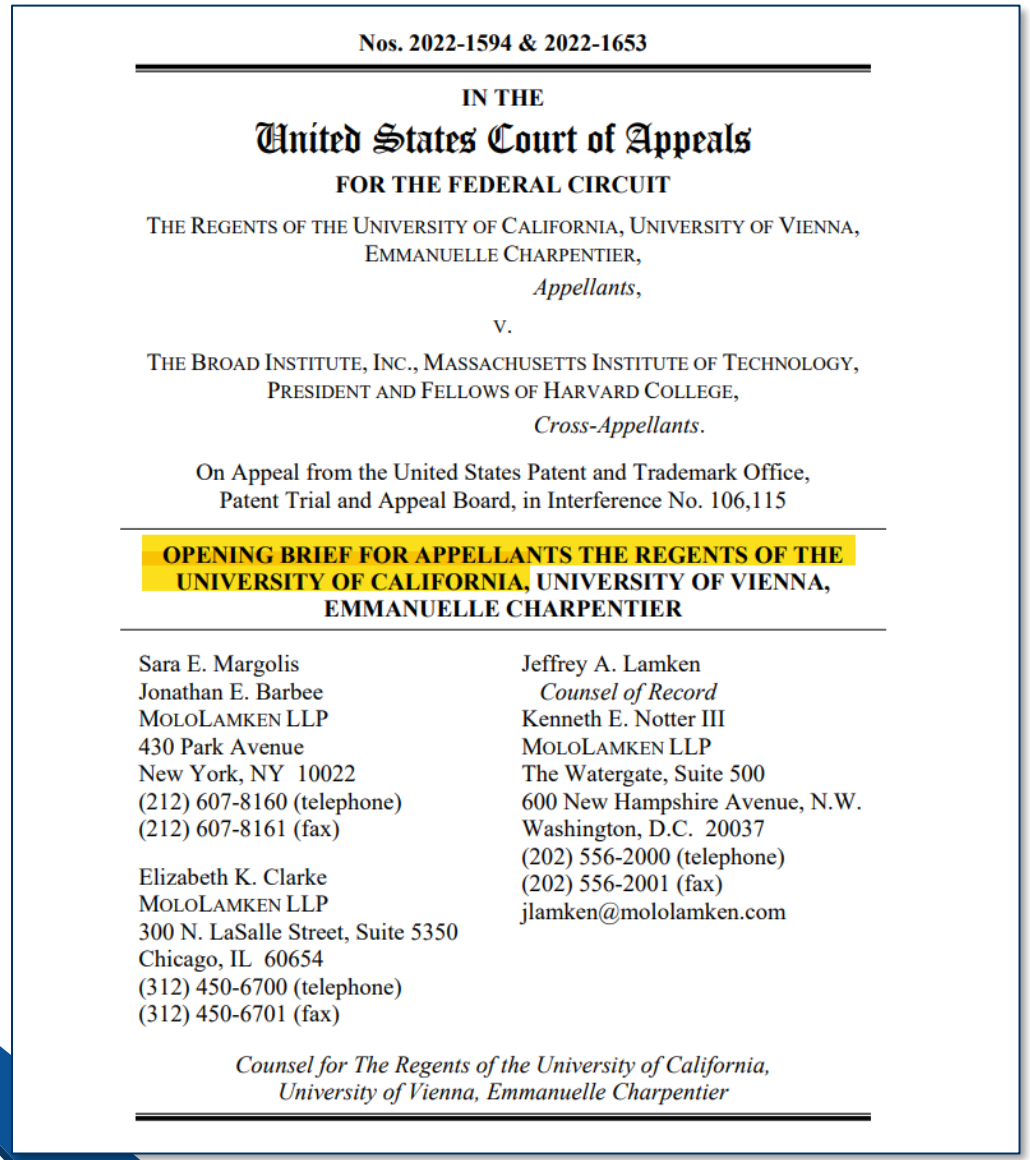
CVC v. Broad (PTAB Decision 2022)

"***CVC does not direct us to evidence that any of the inventors had a definite and permanent idea*** of an sgRNA CRISPR-Cas9 system ***that would work*** to edit DNA in a eukaryotic cell, particularly when they encountered what was perceived as design problems in their system at that time."

CVC v. Broad (PTAB Decision 2022)

"***CVC inventors encountered multiple experimental failures before they recognized any success***, even as late as mid-October 2012. Although the CVC inventors developed a system on 1 March 2012 that they hoped would work in eukaryotic cells … they did not have a definite and permanent idea of how to achieve that result as of that date or by the later dates … because of their perception of these multiple failures."

CVC Appeals to Fed. Cir.



Nos. 2022-1594 & 2022-1653

IN THE

United States Court of Appeals

FOR THE FEDERAL CIRCUIT

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, UNIVERSITY OF VIENNA, EMMANUELLE CHARPENTIER,

Appellants,

v.

THE BROAD INSTITUTE, INC., MASSACHUSETTS INSTITUTE OF TECHNOLOGY, PRESIDENT AND FELLOWS OF HARVARD COLLEGE,

Cross-Appellants.

On Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board, in Interference No. 106,115

OPENING BRIEF FOR APPELLANTS THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, UNIVERSITY OF VIENNA, EMMANUELLE CHARPENTIER

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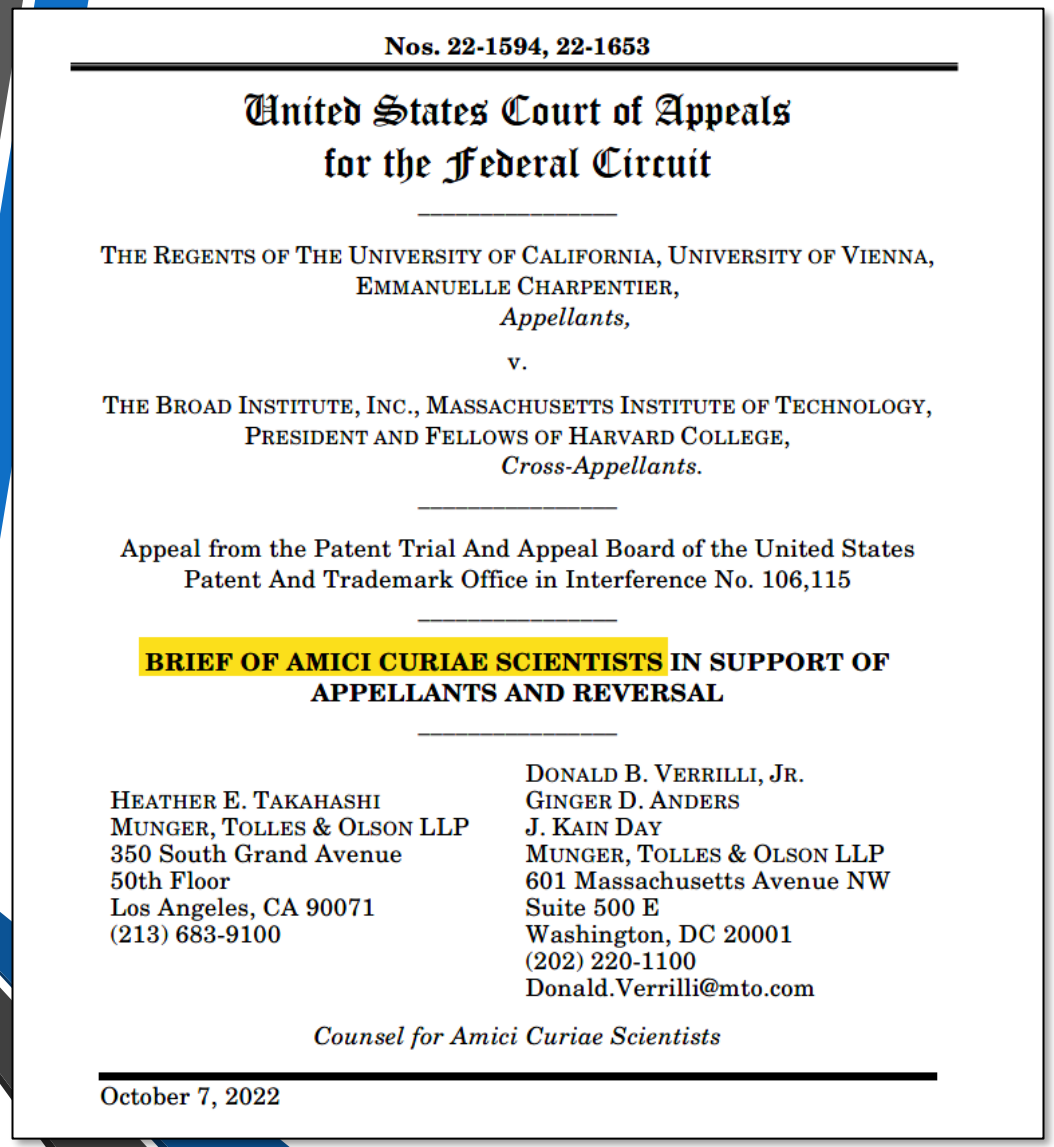
Counsel for The Regents of the University of California, University of Vienna, Emmanuelle Charpentier

"The PTAB erroneously required … that CVC ***know*** its invention would work. That defies precedent."

Amicus Brief



Nos. 22-1594, 22-1653

United States Court of Appeals
for the Federal Circuit

THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, UNIVERSITY OF VIENNA, EMMANUELLE CHARPENTIER,
Appellants,

v.

THE BROAD INSTITUTE, INC., MASSACHUSETTS INSTITUTE OF TECHNOLOGY, PRESIDENT AND FELLOWS OF HARVARD COLLEGE,
Cross-Appellants.

Appeal from the Patent Trial And Appeal Board of the United States Patent And Trademark Office in Interference No. 106,115

BRIEF OF AMICI CURIAE SCIENTISTS IN SUPPORT OF APPELLANTS AND REVERSAL

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October 7, 2022

"***The scientific method requires researchers to approach experiments with objectivity,*** which is precisely what the CVC inventors did here—***expressing professional skepticism*** while confirming their discovery through the routine methods detailed in their patent application"

PTAB decision "***fundamentally misunderstands the scientific method*** and, if upheld, ***would harm science***"

Fed. Cir. Appeal

"An inventor's belief that his invention will work or his reasons for choosing a particular approach are irrelevant to conception."

Because "***the discovery that an invention actually works is part of its reduction to practice***," the "inventor need not know that his invention will work for conception to be complete" or even have "a reasonable expectation that the invention will work for its intended purpose."

***Burroughs Wellcome* (Fed. Cir. 1994)**

Fed. Cir. Appeal

"The conception inquiry asks whether the inventors embraced the invention in their minds as of the date alleged. ***Whether or not subsequent testing succeeded or failed***, or even took place, ***does not determine whether conception was complete*** as of that date."

In re Jolley **(Fed. Cir. 2002)**

CVC v. Broad (Fed. Cir. Decision)

"Board legally erred by conflating the distinct legal standards for conception and reduction to practice"

"The ***Board legally erred by requiring Regents' scientists to know their invention would work***"

"The ***Board*** … ***legally erred by focusing on Regents' scientists' statements of uncertainty***, without considering whether those statements led to modifications in their experiments that substantively changed their original idea"

CVC v. Broad (Fed. Cir. Decision)

"The ***Board erred in its analysis by failing to consider routine methods or skill***, and, instead, focusing almost entirely on Regents' scientists' statements about perceived experimental difficulties and doubts about success."

"The ***Board erred in failing to consider purported experimental success by others*** presented on the record . . . . "

Takeaways

- Conception and reduction to practice are different.
- Inventors are the individuals who conceive of the invention, not those who reduce it to practice.
- Inventors do not need to know that their invention will work.
- Experimental success is not required for conception.
- Scientific skepticism and discourse do not undermine conception.
- However, correspondence reflecting uncertainty may be used to argue that the inventors did not have a definite and permanent idea.